UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

BLUE CROSS AND BLUE SHIELD OF KANSAS CITY, Plaintiff, v. GS LABS LLC, Defendant.	)	Cause No.: 4:21-cv-00525-FJG

BLUE KC'S SUGGESTIONS IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT

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Each of GS Labs, LLC's counterclaims depend on its contention that it administered FFRCA-covered COVID-19 diagnostic testing services to Blue KC members. However, Blue KC estimates that GS Labs, LLC ("GSL") has produced corresponding consent and intake forms and test results for ***only approximately 13%*** of the claims identified on GSL's most recent claim summary (GS LABS 00000002-B). Exhibit A & Exhibit A27. Based on GSL's document production to date, however, GSL is unable to demonstrate that a large majority of its claims were (1) diagnostic in nature and/or (2) were actually administered and produced test results. GSL's inability or unwillingness to produce core documents critical to its Counterclaim requires the entry of partial summary judgment on those claims for reimbursement that GSL cannot substantiate with admissible evidence.

I. UNCONTROVERTED MATERIAL FACTS

1. GSL's Counterclaim arises from its contention that it "submitted claims relating to COVID-19 testing of Blue KC's members totaling over $9.7 million" Doc. No. 4, ¶ 6.

2. GSL rests its Counterclaim on the Family First Coronavirus Response Act (FFRCA) and the CARES Act. *See* Doc. No. 4, Counterclaim, ¶¶ 6, 39-41, 49, 51, 54-56, 71-72, 75-76, 80, 90-93, 101-107, 111-119, 121, 126, 131, 137, 142, 146, 148, 154, 165, 173, 179, 187, & 190.

3. GSL has not specifically identified in its pleading the claims for which it seeks reimbursement. *See generally* Doc. No. 4; *see also* Doc. No. 24 (arguing claim-specific detail improperly omitted from pleading).

4. On September 15, 2021, GSL served its Rule 26(a) automatic disclosures. Exhibit A1.

5. In its Rule 26(a) disclosures, GSL identified "Blue KC Member Patient Records including consent document and test results" as records it may use to support its defenses or claims. Exhibit A1.

6. GS Labs further stated in its Rule 26(a) disclosures that it would "produce the documents [described in its Rule 26(a) disclosures] within seven (7) days of the Court issuing a Protective Order." Exhibit A1.

7. On August 30, 2021, Blue KC requested that GSL produce "all medical records, certifications, billing records, records of collections or write-offs, consent forms, physician or nurses orders, or other records or data collected or generated as a result of any Blue KC member's receipt of services from GSL." Exhibit A2.

8. On September 30, 2021, GSL responded to this discovery by stating that "once the parties have an executed protective order, GS Labs will provide a rolling production of the thousands of medical records at issue." Exhibit A3.

9. The Court entered a stipulated protective order on October 14, 2021. Doc. No. 56.

10. GSL has not produced intake and consent forms and test results for the large majority of the testing for which it seeks relief. *See* Exhibit A, A27

11. GSL has also not agreed to complete its production of the records in question before the close of fact discovery on May 15, 2022. Exhibit A, paragraph 22.

12. On or about December 29, 2021, GSL produced a document labeled GS LABS 00000002-A. GS LABS 00000002-A is marked as Exhibit A4.

13. Exhibit A4 contains approximately 13,632 unique claims and $10,128,722 in charges for services purportedly administered between November 28, 2020, and November 8, 2021. Exhibit A4

14. Exhibit A4 includes a "primary diagnosis code" for each of the claims and over 99% of the codes supplied are Z20.822 or Z20.828.[1] Exhibit A4

15. On or about February 4, 2022, GSL produced GS LABS 00000002-B. GS LABS 00000002-B is marked as Exhibit A5.

16. Specifically, Exhibit A5 contains approximately 20,473 unique claims and $13,056,082 in charges for services purportedly administered between November 28, 2020, and January 10, 2022. Exhibit A5.

17. Unlike GS LABS 00000002-A, GS LABS 00000002-B does not include a column identifying primary diagnosis code. *Compare* Exhibit A4 *with* Exhibit A5.

18. GSL has also produced reimbursement claim forms ("Form 1500s") that include claim information such as patient name, date of purported service, and diagnostic code. Examples are attached and marked as Exhibits A6, A7, A8, A9, A10, A11.

19. Blue KC estimates that GSL has produced corresponding consent and intake forms and test results for ***only approximately 13%*** of the claims identified on GSL's most recent claim summary (GS LABS 00000002-B). Exhibit A & Exhibit A27.

20. With respect to the limited number of consent and intake forms produced by GSL in this litigation, those records contain material information inconsistent with the claim forms and summary claim data GSL produced. *See infra* ¶¶ 21-28.

[1] Blue KC requests the Court take judicial notice of the translation of these codes. These codes were implemented by the Centers for Disease Control and Prevention's National Center for Health Statistics. *See generally*, https://www.cdc.gov/nchs/data/icd/Announcement-New-ICD-code-for-coronavirus-19-508.pdf and https://www.cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf (last visited March 7, 2022).

21. Blue KC's retained expert, R. Garrison Harvey, estimated that 47% of patient intake and consent forms produced by GSL contains diagnostic information inconsistent with the corresponding Form 1500's and the summary billing data. Exhibit A12, pg. 45-46.

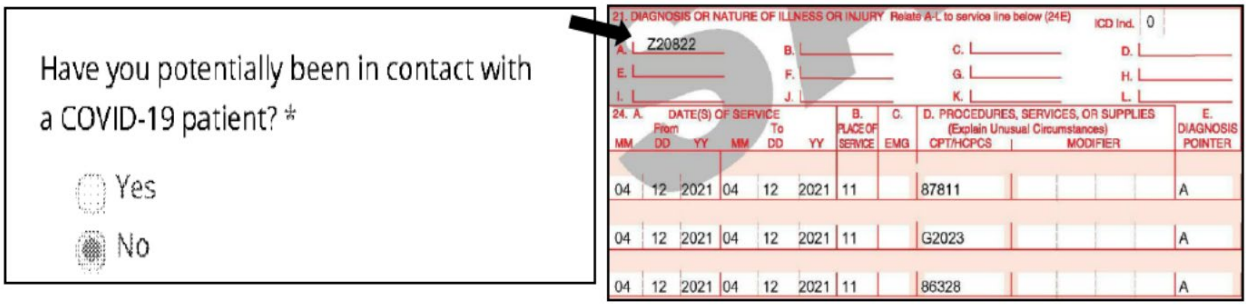
22. By way of example only, the following table summarizes a small subset of the documents produced:

Patient Initials	Diagnostic Code Used by GSL on the GS LABS 00000002-A	Diagnostic Code Used by GSL on Form 1500	Translation of Diagnostic Code Used by GSL on Form 1500 and GS LABS 00000002-A	Did patient report contact with a COVID-19 patient on the consent and intake form?
S.C.	Z20.822	Z20.822	Contact with and (suspected) exposure to COVID-19	***No.***
R.F.	Z20.822	Z20.822	Contact with and (suspected) exposure to COVID-19	***No.***
E.H.	Z20.822	Z20.822	Contact with and (suspected) exposure to COVID-19	***No.***
A.H.	Z20.828	Z20.828	Contact with and (suspected) exposure to other viral communicable diseases.	***No.***
Q.O.	Z20.822	Z20.822	Contact with and (suspected) exposure to COVID-19	***No.***
T.S.	Z20.822	Z20.822	Contact with and (suspected) exposure to COVID-19	***No.***

Compare Summary Claim Data Exhibit A4, Form 1500 Exhibits A6, A7, A8, A9, A10, A11 *with* Intake and Consent Form Exhibits A13, A14, A15, A16, A17, A18.

23. For example, Patient S.C.'s consent and intake form and the associated Form 1500 contain the following:[2]

[2] An arrow highlights the diagnostic code. That arrow does not appear in the original.



24. Similarly, the diagnostic code on the summary claims data is inconsistent with S.C.'s medical records. *See* Exhibit A4, line 34888-34890.

25. Beyond these discrepancies, GSL has also produced Form 1500s for patients that are not identified on Exhibit A4.

26. As an example, GSL produced the following Form 1500s in this litigation which do not appear on Exhibit A4.

a. GS LABS 00074526. Exhibit A19.

b. GS LABS 00074507. Exhibit A20.

c. GS LABS 00074493. Exhibit A21.

27. The intake and consent forms associated with each of these Form 1500s was produced and bates labeled:

a. GS LABS 00074522. Exhibit A22.

b. GS LABS 00074502. Exhibit A23.

c. GS LABS 00074489. Exhibit A24.

28. Eric Rubenstein discusses the significance of false or inconsistent information in claim information in his report dated March 1, 2022. Exhibit A25, pg. 7 & 27-28.

29. Several witnesses with firsthand knowledge of GSL's operations reported frequent serious problems with the administration of COVID-19 tests and GSL's failure to deliver testing

results to patients. *See generally* declaration of KT Thiessen (Exhibit B) and Stacey Johnson-Sweany (Exhibit C).

30. Mr. Thiessen, a former assistant site manager at GSL's Lee's Summit facility, reported:

> I observed many instances - at least weekly and potentially more - where one person's results were mixed up with another person's results. On many occasions one person's results were mixed up and placed in the wrong person's file. Other times, incorrect results were accidently marked on the records. Customers called frequently about results not being sent on all three types of tests or the wrong person's results being delivered.

Exhibit B.

31. Ms. Johnson-Sweany a former site manager at GSL's Lee's Summit facility reported:

> I observed many serious problems with the administration of COVID-19 tests and delivery of results at GS Labs. As an example, on many occasions one person's results were mixed up and placed in the wrong person's file. Other times, incorrect results were accidently marked on the records. Customers called frequently about results not being sent on all three types of tests or the or the wrong person's results being delivered . . . I observed problems with testing like those described above approximately 10 times per day and believe they may have impacted many more tests.

Exhibit C.

32. An example of a GSL test result is included as Exhibit A26.

II. BACKGROUND ON THE FAMILIES FIRST CORONAVIRUS RESPONSE ACT

Although the Families First Coronavirus Response Act requires that insurers and other group health plans generally provide coverage for certain COVID-19 testing, it does not require insurers pay claims simply because a bill for a purported testing was submitted. Instead, the testing must have been (1) actually performed and (2) be diagnostic. Nothing in the FFRCA prevents plans and insures from combatting fraud and abusive claims. *See* Department Guidance, FAQ 44 Q2.[3] ("[t]o the extent not

[3] https://www.cms.gov/files/document/faqs-part-44.pdf

inconsistent with the FFCRA's prohibition on medical management, plans and issuers may continue to employ programs designed to detect and address fraud and abuse.")

Section 6001(a) of the FFCRA provides:

> A group health plan and a health insurance issuer offering group or individual health insurance coverage . . . shall provide coverage, . . . for the following items and services furnished during any portion of the emergency period . . . .:
>
> (1) In vitro diagnostic products (as defined in section 809.3(a) of title 21, Code of Federal Regulations) for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19 that are approved, cleared, or authorized under section 510(k), 513, 515 or 564 of the Federal Food, Drug, and Cosmetic Act, and the administration of such in vitro diagnostic products.
>
> (2) Items and services furnished to an individual during health care provider office visits (which term in this paragraph includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product described in paragraph (1), but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product.

Departmental guidance clarifies that tests administered on patients without symptoms of COVID-19 or exposure to another person with COVID-19 are not diagnostic and therefore, need not be reimbursed:

> **Q2. May plans and issuers distinguish between COVID-19 diagnostic testing of asymptomatic people that must be covered, and testing for general workplace health and safety, for public health surveillance, or for other purposes not primarily intended for individualized diagnosis or treatment of COVID-19?**
>
> Yes. Plans and issuers must provide coverage without imposing any cost-sharing requirements (including deductibles, copayments, and coinsurance), prior authorization, or other medical management requirements for COVID-19 diagnostic testing of asymptomatic individuals when the purpose of the testing is for individualized diagnosis or treatment of COVID-19. However, plans and issuers are not required to provide coverage of testing such as for public health surveillance or employment purposes.

https://www.cms.gov/files/document/faqs-part-44.pdf.

> **Q5. Is COVID-19 testing for surveillance or employment purposes required to be covered under section 6001 of the FFCRA?**

> No. Section 6001 of the FFCRA requires coverage of items and services only for diagnostic purposes as outlined in this guidance. Clinical decisions about testing are made by the individual's attending health care provider and may include testing of individuals with signs or symptoms compatible with COVID-19, as well as asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2, that is determined to be medically appropriate by the individual's health care provider, consulting CDC guidelines as appropriate. However, testing conducted to screen for general workplace health and safety (such as employee "return to work" programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is beyond the scope of section 6001 of the FFCRA.

https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf.

The FDA explains the difference between a "diagnostic test" and a "screening test."

> Diagnostic testing: Diagnostic testing identifies current infection at the individual level and is performed when a person has signs or symptoms of infection, or when a person is asymptomatic but has recent known or suspected exposure. Most tests the FDA has authorized are for diagnosing SARS-CoV-2 in people suspected of COVID-19 by their health care provider, whether or not they are symptomatic. Some diagnostic tests are authorized for use only in symptomatic individuals.
>
> Screening testing: Screening testing looks for individual infections in a group even if there is no reason to suspect those individuals are infected. Screening involves testing asymptomatic individuals who do not have known or suspected exposure to COVID-19 in order to make individual decisions based on the test results. The FDA has authorized some tests for screening.

See https://www.fda.gov/media/146666/download

III. STANDARD FOR SUMMARY JUDGMENT AGAINST PARTY WITH BURDEN OF PRODUCTION

Summary judgment is proper if the evidence, when viewed in the light most favorable to the nonmoving party, shows that there is no genuine issue of material fact in dispute and that the defendant is entitled to entry of judgment as a matter of law. Fed. R. Civ. P. 56. Rule 56(c) requires "the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett,* 477 U.S. 317, 322 (1986).

"Where the nonmovant bears the ultimate burden of proof on a particular claim at trial . . . the movant may [] demonstrate that the nonmovant's evidence is insufficient to establish an essential element of his or her claim . . . ." *Roath v. Chrysler Corp.*, 2000 WL 35527086, at *1 (W.D. Mo. Feb. 2, 2000). The burden on the party moving for summary judgment "is only to demonstrate . . . that the record does not disclose a genuine dispute on a material fact." *City of Mt. Pleasant, Iowa v. Associated Elec. Co–Op.,* 838 F.2d 268, 273 (8th Cir.1988). "This burden is met when the moving party identifies portions of the record demonstrating an absence of a genuine issue of material fact." *Budd v. ADT Sec. Sys.*, 1996 WL 932707, at *4 (W.D. Mo. Mar. 12, 1996), aff'd sub nom. *Budd v. ADT Sec. Sys., Inc.*, 103 F.3d 699 (8th Cir. 1996). In other words, if the dispositive issue is one on which the nonmoving party will bear the burden of proof at trial, the moving party may satisfy its burden by pointing out that the evidence in the record is insufficient with respect to an essential element of the nonmoving party's claim. *See Celotex Corp.*, 477 U.S. at 325.

If the moving party meets the requirement of demonstrating insufficient evidence, the burden shifts to the nonmoving party who "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248-49 (1986). The trial judge then determines whether a trial is needed. *Id.* at 250 ("[W]hether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.") The nonmovant may not rest upon the pleadings but must identify specific facts that establish a genuine issue for resolution. *See, e.g., id.* at 248*; Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) ("Rule 56 'mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.'") (quoting *Celotex Corp.*, 477 U.S. at 322). A claimant cannot "sit back and simply poke holes" in the motion. *Fitzpatrick v. Catholic Bishop of Chicago*, 916 F.2d 1254, 1256 (7th Cir. 1990);

Buford v. Tremayne, 747 F.2d 445, 447 (8th Cir. 1984). Rather, the claimant must come forward with admissible evidence of specific facts that "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (citations omitted). "[A] complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex Corp.*, 477 U.S. at 323.

IV. ANALYSIS

To date, GSL has been unwilling or unable to produce documents supporting its Counterclaim seeking over $9.7 million for diagnostic testing. Each of its legal theories, to the extent these claims were to survive the pending motion to dismiss (Doc. No. 23), are dependent on FFCRA-covered testing actually being administered. Doc. No. 4, Counterclaim, ¶¶ 39-41, 49, 51, 54-56, 71-72, 75-76, 80, 90-93, 101-107, 111-119, 121, 126, 131, 137, 142, 146, 148, 154, 165, 173, 179, 187, & 190.

Nevertheless, for the large majority of the claims at issue, GSL has not produced core records related to these purported testing services. To date, GSL is unable or unwilling to produce records required to be maintained under state law. *See* Mo. Rev. Stat. 334.097 (requiring the maintenance of patient records showing "the current status of the patient, including reason for the visit," "observation of pertinent physical findings," "assessment and clinical impression of diagnosis," "[p]lan for care and treatment, or additional consultations or diagnostic testing . . . ." and "any informed consent for office procedures"); KAR 100-24-1 (requiring the maintenance of adequate patient documentation including "significant information concerning the patient's condition," "reflect what examinations, vital signs, and tests were obtained, performed, or ordered and the findings and results of each," and "reflect the initial diagnosis and the patients initial reason for seeking the licensee's service"). These records were identified as part of GSL's Rule 26(a) disclosures, and have been requested by Blue KC through a Rule

34 Request. Despite these requests and GSL's agreement to produce the records, GSL has only produced a fraction of the records in question.

GSL summary claim data is deficient because it fails to include diagnostic data (Exhibit A5) and is contradicted by patient intake and consent forms (Exhibit A4). Neither document is authenticated or admissible evidence. Further, summary charts are inadmissible where the underlying records have not been made available for inspection or produced. *See* F.R.E. 1006; *White Industries, Inc. v. Cessna Aircraft Co.*, 611 F. Supp. 1049, 1069-70 (W.D. Mo. 1985) (noting that for summary evidence to be admissible under F.R.E. 1006 it: (1) "must be of 'voluminous writings, recordings or photographs which cannot be conveniently examined in court'" (2) "the proponent of the evidence must establish that the 'underlying writing, recordings or photographs' are themselves admissible in evidence," (3) "the originals or duplicates of the underlying materials must be made available for examination or copying by the other parties, at a reasonable time and place," and (4) "a summary must be an *accurate* summarization of the underlying materials involved.") (emphasis in original) (citations omitted). Here, GSL has not produced the records underlying its summaries.

As explained in the Report of Gary Harvey, the summary claim data is contradicted by apparent statements of the patients in the intake and consent forms. Exhibit 12, ¶ 108-113; s*ee also* Exhibit 25 pages 27-28, 38 (discussing significance of inconsistent information).

Further, Blue KC has produced evidence that certain testing results were not reliably delivered to patients. *See* Exhibit B, C. These declarations cast further doubt on the summary data for which GSL has failed to produce the underlying documents. HHS-OIG Senior Special Agent Eric Rubenstein (retired) opined that the failure to produce the patient records was indicative of the testing not being administered as billed, the records being maintained so poorly that GSL's results were not reliable, or GSL's effort to hide the records from additional scrutiny. *See* Exhibit A25 p. 28.

In order for a COVID-19 testing provider to demonstrate it is entitled to reimbursement under the FFCRA, it must, at a bare minimum, produce medical records or other admissible evidence which would demonstrate that it is entitled to reimbursement under FFCRA. For at least an estimated eighty-seven percent of the claims identified in its most recent summary claim data, GSL has failed to make this preliminary and necessary showing. GSL's lack of evidence when considered in light of other circumstances described in this motion is sufficient to shift the burden to GSL to set forth specific facts showing that there is a genuine issue for trial on the claims that remain unsubstantiated. *Anderson,* 477 U.S. at 248. If GSL cannot present evidence to substantiate its Counterclaim, partial summary judgment should be granted.[4]

GSL will not be able to demonstrate that it administered over $9.7 million of FFCRA-covered COVID-19 testing to Blue KC's members. GSL's failure to produce necessary records to substantiate its claims demonstrates that it is unable to meet its burden to support its counterclaims for all claims not included on Exhibit A27.3. Blue KC has made a showing sufficient to shift the burden to GSL to produce competent, admissible evidence substantiating the large majority of its claims. Based on the lack of production to date, it appears that GSL is unable to satisfy its burden.

CONCLUSION

WHEREFORE, Blue KC respectfully requests that this Court GRANT Blue KC's Motion for Partial Summary Judgment on GSL's Counterclaim, enter judgment for Blue KC and against GSL with to respect to all claims not identified on Blue KC's Exhibit A27.3, and award any and all further relief that this Court deems is just and warranted under the circumstances.

[4] For the Court's convenience Exhibit A27.3 is a list of all claims Blue KC is not currently seeking partial summary judgment.

Respectfully Submitted,

CAPES, SOKOL, GOODMAN & SARACHAN, P.C.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing was served on all parties of record by filing a copy of the same with the Court's electronic filing system this 10th day of March, 2022.

/s/ Aaron E. Schwartz